

World-Class Program

There is a large and increasing need for current and future pharmaceutical and medical device professionals, regulators, entrepreneurs, and scientists to have specialized training in translating research into new interventions for safe and effective medical products. This initiative supports workforce growth through mitigating barriers and creating incentives to elevate employee satisfaction and performance.

Together, the University of Arizona and C-Path, are delivering a world-class Regulatory Science program to professionals across the globe in a flexible, engaging, and highly effective way.

We accomplish this through strategic partnerships with organizations that are committed to employee education and development. Employees of partner organizations can receive a tuition reduction and on-site executive and continuing education programs on hot and emerging topics in regulatory science.

APPLY TODAY:

<https://law.arizona.edu/health>



 THE UNIVERSITY
OF ARIZONA

+

 CRITICAL PATH
INSTITUTE

GRADUATE CERTIFICATE IN REGULATORY SCIENCE



Contact

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This interprofessional graduate program consists of four courses and one speaker series designed to be completed part-time in one year.

The courses provide students with the knowledge and tools to bridge the path from early discovery and development to bringing medical products to market.

All courses may be applied to a **Master of Legal Studies in Health Law & Policy**.

Course Guide

Fall Session I (August-October)

DRUG DISCOVERY, DEVELOPMENT AND MARKETING OBLIGATIONS (LAW 576A)

This course navigates the drug development to cover the full range of drug regulation, including drug discovery, innovative drug development tools, and the post-approval phase. The course includes FDA and international regulatory perspectives on the costs involved to bring drugs through the clinical trials to market in the US and abroad.

Fall Session 2 (October-December)

REGULATORY SCIENCE CASE STUDY PROJECT (LAW 589A)

There are numerous needs in regulatory science that companies are faced with every day. This course provides an opportunity for students to integrate and apply their knowledge to real-world challenges in regulatory science. Industry leaders will present case-based projects where students work in teams to discuss and problem-solve multifaceted issues on a current or emerging topic in regulatory science.

Fall & Spring

HOT TOPICS & EMERGING ISSUES IN REGULATORY SCIENCE (LAW 695D)

The colloquium features leaders in the field presenting on cutting-edge issues in regulatory science. This course explores the role of executive agencies, such as the FDA, in ensuring safe and effective products to promote public health and address challenges for enforcement in a globalized world.

Spring I (January-March)

CLINICAL RESEARCH ETHICS (LAW 575A)

This course explains the ethical principles underlying regulations and guidance governing clinical trials, especially as the principles pertain to informed consent, risk-benefit disclosure, and conflicts of interest. The course also outlines the elements and design of clinical trials, including federal regulations for research with human subject participants, with vulnerable populations, and international research ethics. The course concludes with research ethics in big data.

Spring 2 (March-May)

DEVELOPMENT & INNOVATION: BIOLOGICS, DEVICES, AND DIAGNOSTICS (LAW 577A)

What are the fundamental incentives for development in the biomedical space? The topics covered in this course include introducing key concepts in oversight by the Food and Drug Administration, biologics and biosimilars, regulation of diagnostics, along with the medical device development and approval process. The course concludes with a survey of Intellectual Property rights regime for medical products and the regulatory challenges in international markets.

Current Students

Our students have a strong and diverse range of backgrounds. Most have five or more years of experience in regulatory science, as administrators, research scientists, and entrepreneurs.



"My training took place in Europe and there are differences in regulations with the FDA/EMA. I look forward to a refresher as well as a learning experience, and an opportunity to interact with a variety of people."

Emmanuelle Meuillet, Research Associate Professor, Nutritional Sciences at University of Arizona and CEO of Theraxen Technologies