

Gain in-demand medical writing skills that will help elevate your career in healthcare or medical communications.

The University of Chicago's non-credit certificate program in Regulatory Writing gives you the training you need to write submissions to the FDA and other regulatory bodies. Building on the strengths of our Medical Writing and Editing program, these courses will provide you with highly technical, high-demand, professionally valuable writing skills in as little as three months, part-time.



Regulatory Writing

Format	Online
Duration	3-36 months
Class length	7 weeks
Contact hours earned	22.5 per course
Investment	\$1,640 per course \$3,280 for certificate

Be in demand in just three months

The Regulatory Writing certificate delivers key competencies to launch your career. You will learn to identify, edit, and create the components of a biomedical regulatory packet; navigate the FDA submission and auditing process; prepare investigational new drug applications; and create submissions for different categories of biomedical research including vaccines, devices, and more.

The UChicago Edge

Our professional courses take innovative learning approaches that uphold the University of Chicago's distinct brand of academic excellence while driving career advancement.



- Synchronous class sessions engage students with instructors and peers.
- Content-specific and networking webinars foster extracurricular training and valuable professional connections.
- Professional development services include resume review and more.
- Program administrators support students throughout the certificate and beyond, from individual advising sessions to alumni services.

Targeted teaching from industry professionals

Our program instructors are experts crafting current regulations and shaping the ethics and future of the healthcare communication industry. With years of experience in regulatory affairs and healthcare compliance, our instructors provide knowledge that you can start applying to your career today.

[professional.uchicago.edu/
regulatory-writing/instructors](https://professional.uchicago.edu/regulatory-writing/instructors)



Regulatory Writing Curriculum

2 core courses

- **Introduction to Regulatory Writing**

This course will equip students with the tools to compile the components of a biomedical regulatory packet for submission to regulatory and oversight bodies such as the FDA, IRB, and IBC.

- **Regulatory Intelligence**

This advanced course will cover FDA submissions, regulatory writing, supportive documentation for major clinical trial milestones, responding to regulatory review, and writing about regulations. Students will learn the intricacies of FDA device, drug, and biologic submissions and gain familiarity with preparing and submitting of required regulatory documents.

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Sample Certificate



Alumni Scholarship

Our alumni scholarship allows graduates of non-credit certificate programs to receive a 20% scholarship on:

- Any additional elective from the same certificate
- Any single new certificate course that does not require a prerequisite
- Any class in any other UCPE certificate program with no application fee

\$75,000–95,000

The median pay for medical writers in 2022 according to Glassdoor.

“My goal is to change how students see regulations. I want to teach them how to approach regulations in an expansive way so they see the opportunities.”

Leah Carter, Senior Regulatory and Compliance Analyst with University of Chicago Medicine and Instructor in the Regulatory Writing Non-credit Certificate Program