URBEST Internship Opportunity

- Company, Agency, Office or Division hosting this Internship:

URMC - Office of Regulatory Support

- Title of Internship:

Regulatory Affairs

- Description of the Internship:

This internship will be for a student or postdoc who is interested in Regulatory Affairs. The trainee will learn about the process of how drugs and medical devices are brought from the design and concept and research phase to the regulatory agency and finally through to patient testing and use. This training period would also provide the intern with the background knowledge to formulate different regulatory paths; this includes the potential regulatory options, the pros and cons of the various pathways, and why one pathway would be selected before another pathway.

In addition to gaining core knowledge in Regulatory Affairs, the trainee could propose an additional project which would be guided and assisted by the mentor. several complementary projects Work on an additional project would require the intern to first gain relevant regulatory skills and become familiar with regulations that govern the clearance, approval and use of medical therapeutics.

- Approximate length of time to be spent at this internship: (e.g., 2-4 weeks or 4-6 months)

4-6 months

- Approximate number of hours to be spent on a recurring basis: (e.g., 40hrs/week or 3-5hrs/week)

3-6 hours / week

- What is the goal of this internship opportunity for the trainee?

The goal of this training opportunity is for the intern to understand how the FDA regulates drugs and medical devices, how investigators in both university and industry settings submit to the FDA, and how to interact with the agency.

- What are the objectives for the participant during the internship opportunity? (add more if needed)
  1. Learn about how the FDA regulates drugs and medical devices
  2. Understand the interactions with FDA and other relevant regulators
  3. Be able to describe how an investigator would position their project for a successful regulatory outcome
  4. Describe the most common process of 'drug repurposing' which is used at the University
  5. Be able to distinguish between the drug and medical device processes

- Will there be any formal training, coursework or examinations involved? If yes, please provide details:

Yes. Two online courses, *Orientation to Requirements for FDA Investigational New Drug (IND) Application* and *Orientation to Medical Devices and the Requirements for an FDA Investigational Device Exemption (IDE) Application*, will be required for the intern to complete. These courses are hosted in Blackboard and

would be expected to take ~ 2-3 hours each to complete. Credit for these courses will be automatically transferred to the intern's HRMS file. In addition, if the opportunity arises, the intern will be asked to take part in 1-2 individual-based trainings that will be given to investigators as they come through the Office of Regulatory Support requesting assistance.

- Responsibilities and duties of the intern:

The intern will be asked to schedule a few hours each week to work with the mentor. These hours may vary week to week and can be tailored to fit the mentor's and mentee's schedule for each week. The Intern will also be asked to be a silent observer in regulatory meetings, assist with regulatory research such a searching for predicate devices or analyzing therapeutic package inserts for relevant content, work in the regulatory database and provide their input at different opportunities as they learn more about the processes.

- How will the participant be supervised throughout the internship? And how will they interact with their supervisor / mentor?

The intern will be supervised by the mentor throughout the entire internship opportunity. A desk will be available to the intern in the CTSI suite where the Office of Regulatory Support is located, but most interactions will take place with the mentor in their office.

- Will there be any final project due from the intern at the completion of the internship opportunity? (e.g., summary memo, presentation, final paper)

Not specifically, unless it is decided that the intern will take on a specific project with a concrete end deliverable.

- How will the Intern be evaluated during the program? (e.g., progress reports, periodic reviews)

During the internship opportunity, the internship host and URBEST's Tracey Baas will evaluate the intern using periodic monthly progress reports (what did they actually do). Each progress report will be written by the internship mentor and edited by the intern. The mentor and intern will then discuss the progress report, sign the document, and submit it to the URBEST office. Tracey will set up either a face-to-face meeting or a phone call with the mentor and intern, individually. The first progress report will be an "intake" document (when the student first arrives) and include goals and expectations for the internship. Following progress reports will address performance, achievement of goals, areas for further development and any other information that the mentor and intern deem important.

- How will the Intern be evaluated at the conclusion of the program? (e.g., final report)

At the end of the internship, URBEST's Sarah Peyre or Tracey Baas will assess the intern, using a final reflection/analysis of the experience. The intern will write the analysis piece, connecting the internship experience to their professional development. They will highlight content knowledge, acquisition of skills and understanding of the workforce, self-assessment of their performance and identification of areas that they still need development. Tracey will set up a group meeting or conference call for a final debrief of both the mentor and the intern.

- If there is any additional information about your internship opportunity that you would like to provide, please include it here:

N/A